

determination in the docket established for the application in FDA's Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(c) FDA will also publish the regulatory review period determination in the FEDERAL REGISTER. The notice will include the following:

- (1) The name of the applicant;
- (2) The trade name and generic name (if applicable) of the product;
- (3) The number of the patent for which an extension of the term is sought;
- (4) The approved indications or uses for the product;
- (5) An explanation of any discrepancies between the dates in the application and FDA records;
- (6) Where appropriate, an explanation that FDA has no record in which to review the date(s) contained in the application; and
- (7) The regulatory review period determination, including a statement of the length of the testing and approval phases and the dates used in calculating each phase.

[53 FR 7305, Mar. 7, 1988, as amended at 59 FR 14364, Mar. 28, 1994]

#### **§ 60.22 Regulatory review period determinations.**

In determining a product's regulatory review period, which consists of the sum of the lengths of a testing phase and an approval phase, FDA will review the information in each application using the following definitions of the testing phase and the approval phase for that class of products.

(a) For human drugs:

(1) The testing phase begins on the date an exemption under section 505(i) of the Act becomes effective (or the date an exemption under former section 507(d) of the Act became effective) for the approved human drug product and ends on the date a marketing application under section 351 of the Public Health Service Act or section 505 of the act is initially submitted to FDA (or was initially submitted to FDA under former section 507 of the Act), and

(2) The approval phase begins on the date a marketing application under section 351 of the Public Health Service

Act or section 505(b) of the Act is initially submitted to FDA (or was initially submitted under former section 507 of the Act) and ends on the date the application is approved.

(b) For food and color additives:

(1) The testing phase begins on the date a major health or environmental effects test is begun and ends on the date a petition relying on the test and requesting the issuance of a regulation for use of the additive under section 409 or 721 of the Act is initially submitted to FDA.

(2) The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 or 721 of the Act is initially submitted to FDA and ends upon whichever of the following occurs last:

(i) The regulation for the additive becomes effective; or

(ii) Objections filed against the regulation that result in a stay of effectiveness are resolved and commercial marketing is permitted; or

(iii) Proceedings resulting from objections to the regulation, after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted.

(c) For medical devices:

(1) The testing phase begins on the date a clinical investigation on humans is begun and ends on the date an application for premarket approval of the device or a notice of completion of a product development protocol is initially submitted under section 515 of the Act. For purposes of this part, a clinical investigation is considered to begin on whichever of the following dates applies:

(i) If an investigational device exemption (IDE) under section 520(g) of the Act is required, the effective date of the exemption.

(ii) If an IDE is not required, but institutional review board (IRB) approval under section 520(g)(3) of the Act is required, the IRB approval date.

(iii) If neither an IDE nor IRB approval is required, the date on which the device is first used with human

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subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device.

(2) The approval phase either:

(i) Begins on the date an application for premarket approval of the device is initially submitted under section 515 of the Act and ends on the date the application is approved; or

(ii) Begins on the date a notice of completion of a product development protocol is initially submitted under section 515 of the Act and ends on the date the protocol is declared to be completed.

(d) For animal drugs:

(1) The testing phase begins on the date a major health or environmental effects test is begun or the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, and ends on the date a marketing application under section 512 of the Act is initially submitted to FDA.

(2) The approval phase begins on the date a marketing application under section 512 of the Act is initially submitted to FDA and ends on the date the application is approved.

(e) For purposes of this section, a “major health or environmental effects test” may be any test which:

(1) Is reasonably related to the evaluation of the product’s health or environmental effects, or both;

(2) Produces data necessary for marketing approval; and

(3) Is conducted over a period of no less than 6 months duration, excluding time required to analyze or evaluate test results.

(f) For purposes of determining the regulatory review period for any product, a marketing application, a notice of completion of a product development protocol, or a petition is *initially submitted* on the date it contains sufficient information to allow FDA to commence review of the application. A marketing application, a notice of completion of a product development protocol, or a petition is *approved* on the date FDA sends the applicant a letter informing it of the approval or, by order declares a product development protocol to be completed, or, in the case of food and color additives, on the

effective date of the final rule listing the additive for use as published in the FEDERAL REGISTER or, in the case of a new animal drug in a Category II Type A medicated article, on the date of publication in the FEDERAL REGISTER of the notice of approval pursuant to section 512(i) of the Act. For purposes of this section, the regulatory review period for an animal drug shall mean either the regulatory review period relating the drug’s approval for use in nonfood-producing animals or the regulatory review period relating to the drug’s approval for use in food-producing animals, whichever is applicable.

[53 FR 7305, Mar. 7, 1988, as amended at 57 FR 56262, Nov. 27, 1992; 64 FR 400, Jan. 5, 1999]

### § 60.24 Revision of regulatory review period determinations.

(a) Any person may request a revision of the regulatory review period determination within 60 days after its initial publication in the FEDERAL REGISTER. The request shall be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The request shall specify the following:

(1) The type of action requested;

(2) The identity of the product;

(3) The identity of the applicant;

(4) The FDA docket number; and

(5) The basis for the request for revision, including any documentary evidence.

(b) Unless the applicant is the person requesting the revision, the applicant shall respond to the request within 15 days. In responding to the request, the applicant may submit information which is relevant to the events during the regulatory review period but which was not included in the original patent term restoration application. A request for a revision is not equivalent to a due diligence petition under § 60.30 or a request for a hearing under § 60.40. If no response is submitted, FDA will decide the matter on the basis of the information in the patent term restoration application, request for revision, and FDA records.

(c) FDA shall apply the provisions of § 60.22 in considering the request for a